

## REMARKS

Claims 19-20 and 22-36 are pending in this application. Claims 1-18, 21, and 37-46 were previously cancelled. Claims 19-20, 22-29, 31, 32, and 34-36 have been allowed. Claims 19-20 and 22-36 are cancelled herein and new claims 47-64 are presented as discussed with the Examiner in the telephone conference of June 14, 2005. Upon entry of these amendments, claims 47-64 are pending and under active consideration.

New claims 47-49 and 51-64 correspond generally to previously pending claims 1-18, 21, and 37-46. For the Examiner's convenience, the new claims are presented in the appendix hereto in marked-up form from the previously pending claims to show the re-numbering of the claims and the updating of dependency of claims 49 and 51-64, as well as the minor amendments for grammatical clarity and correction of antecedent basis.

Dependent claim 50 has been added to provide antecedent basis for claims 58-64. Support for claim 50 may be found throughout the specification as filed, notably at pages 6-7 of the specification as filed.

Dependent claims 52 and 53 reflect a minor grammatical amendment for clarity, replacing "having" with "and has." Support may be found throughout the specification as filed, notably at page 7 of the specification as filed.

Dependent claim 58 reflects a grammatical clarification of the dosage provided as required by the Examiner.

Dependent claim 61 reflects corrected antecedent basis.

No new matter has been added. Applicant respectfully requests entry of the amendment and remarks made herein into the file history of the present application.

### **1. The rejection under §112, second paragraph should be withdrawn.**

The Examiner has rejected claims 30 and 33 under 35 U.S.C. § 112, ¶2 as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Examiner states that the use of a range terminating in zero contradicts the presence of both the alpha-adrenergic blocker and prostaglandin in the composition.

Applicant has amended prior claim 30, presently presented as new claim 58, to clarify that the alpha-adrenergic blocker and the prostaglandin are present in dosages of less than about 10

mg/ml and less than about 40 µg/ml, respectively. Applicant respectfully asserts that these amendments clarify the claims as required by the Examiner.

## 2. Conclusion

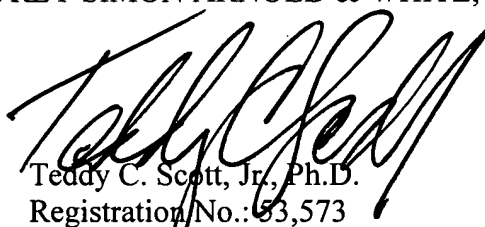
In view of the above amendments and remarks, Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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By:



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## Appendix

### Substitute Claims as “Marked-Up” from Previously Pending Claims

47. (Prior claim 19 – previously amended) A method for the treatment of male erectile dysfunction which comprises administering to a male in need thereof a pharmacologically effective amount of a composition comprising an  $\alpha$ -adrenergic blocker and a prostaglandin in a buffer, wherein the buffer comprises a substrate for nitric oxide synthetase.

48. (Prior claim 20 – presently amended) The method of claim 47 **[[19]]** wherein the  $\alpha$ -adrenergic blocker is phentolamine mesylate, or any pharmaceutically acceptable salt thereof.

49. (Prior claim 22 – presently amended) The method of claim 47 **[[19]]** wherein the prostaglandin is alprostadil.

50. (New) The method of claim 47 wherein the  $\alpha$ -adrenergic blocker is phentolamine mesylate, or any pharmaceutically acceptable salt thereof and the prostaglandin is alprostadil, and wherein the composition is administered in one or more dosages.

51. (Prior claim 23 – presently amended) The method of claim 47 **[[19]]** wherein the buffer comprises L-arginine and, optionally, a pharmaceutically acceptable excipient or carrier.

52. (Prior claim 24 – presently amended) The method of claim 51 **[[23]]** wherein the buffer comprises glycine **having and has** a pH range of from about 3 to about 5.

53. (Prior claim 25 – presently amended) The method of claim 47 **[[19]]** wherein the buffer comprises a mixture of arginine and glycine **having and has** a pH range of from about 3 to about 5.

54. (Prior claim 26 – presently amended) The method of claim 47 **[[19]]** wherein the buffer comprises glycine and L-arginine in a weight ratio of about 1:20.

55. (Prior claim 27 – presently amended) The method of claim 53 **[[25]]** wherein the buffer further comprises benzyl alcohol and mannitol and has a pH range of from about 3 to about 5.

56. (Prior claim 28 – presently amended) The method of claim 50 **[[19]]** wherein the weight ratio of phentolamine mesylate: alprostadil is about 0.5:0.005 to about 5: 0.20.

57. (Prior claim 29 – presently amended) The method of claim 50 **[[19]]** wherein the weight ratio of phentolamine mesylate: alprostadil is about 1:0.01.

58. (Prior claim 30 – presently amended) The method of claim 50 ~~[[19]]~~ wherein the dosage of phentolamine mesylate and alprostadil ~~are in the range of~~ is less than about ~~[[0-]]~~40 µg/ml alprostadil and less than about ~~[[0-]]~~10 mg/ml phentolamine.

59. (Prior claim 31 – presently amended) The method of claim 58 ~~[[19]]~~ wherein the dosage of phentolamine mesylate and alprostadil are in the range of about 1.25-5 mg/ml phentolamine and about 5-20 µg/ml alprostadil.

60. (Prior claim 32 – presently amended) The method of claim 58 ~~[[19]]~~ wherein the dosage of phentolamine mesylate and alprostadil are about 1 mg/ml phentolamine and about 0.01 mg/ml alprostadil.

61. (Prior claim 33 – presently amended) The method of claim 58 ~~30, 31, or 32~~ wherein the dosage of phentolamine mesylate and alprostadil is ~~the vasoactive agents are~~ present in a total volume of 0.5 ml.

62. (Prior claim 34 – presently amended) The method of claim 50 ~~[[19]]~~ wherein the dosage of alprostadil is about 5 µg/ml in a total volume of 0.5 ml.

63. (Prior claim 35 – presently amended) The method of claim 50 ~~[[19]]~~ wherein the dosage of phentolamine is about 1.25 mg/ml in a total volume of 0.5 ml.

64. (Prior claim 36 – presently amended) The method of claim 50 ~~[[19]]~~ wherein the pH range of the buffer is from about 3 to about 7.